

Europäisches Patentamt
European Patent Office
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⑪ Publication number:

0 142 372
B1

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EUROPEAN PATENT SPECIFICATION

- ⑯ Date of publication of patent specification: **25.01.89** ⑮ Int. Cl.⁴: **A 61 B 5/04**
⑯ Application number: **84307882.5**
⑯ Date of filing: **14.11.84**

⑯ Biomedical electrode.

⑩ Priority: **14.11.83 US 551068**

⑯ Date of publication of application:
22.05.85 Bulletin 85/21

⑯ Publication of the grant of the patent:
25.01.89 Bulletin 89/04

⑯ Designated Contracting States:
DE FR GB IT SE

⑯ References cited:
US-A-3 805 769
US-A-3 911 906
US-A-3 993 049
US-A-4 029 086
US-A-4 034 854
US-A-4 117 846
US-A-4 273 135
US-A-4 327 737
US-A-4 353 373

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Courier Press, Leamington Spa, England.

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Description

Background

The invention relates to the field of disposable biomedical electrodes for establishing an electrical connection between the skin of the human anatomy and an electromedical apparatus such as a high impedance electromyograph, electrocardiograph, electrostimulator for pain relief and the like. An automated method of making disposable electrodes is also included within the scope of the invention.

Many types of disposable biomedical electrodes have been introduced in recent years. Typically they comprise (1) a metallic or electrically-conductive carbon terminal member having means for electrical connection to an electromedical apparatus such as an electrocardiograph; (2) an adhesive tape or pad for holding the terminal member in place on the skin; and (3) an electrically-conductive, conformable interfacing material such as an electrolyte gel or paste over the surface of the terminal member which contacts the skin to reduce skin impedance and improve electrical contact between the skin and the terminal member.

Disposable biomedical electrodes have been improved in the last few years by the introduction of electrically conductive pressure-sensitive adhesives to replace conventional electrolyte gels and creams. Such gels are generally messy and unpleasant to use and, because of their high water content, require elaborate packaging to prevent "dry-out" problems. When an electrically-conductive pressure-sensitive adhesive is used as the interfacing material between the terminal member and the skin, a separate adhesive tape or pad to adhere the electrode to the skin may not be necessary, resulting in a smaller, lower-cost disposable electrode.

For ease of connection to the lead wire of an electromedical device, the terminal member of many disposable biomedical electrodes is formed in the shape of the male portion of a snap fastener adapted to engage the female portion of the snap fastener attached to the lead wire of the electromedical device. Such a terminal member comprises a flat, circular portion and a knob-like projection extending perpendicularly therefrom. Such a one-piece terminal member is illustrated in U.S. Patent No. 4,273,135. A one-piece terminal member of this type is difficult to securely anchor to the adhesive pad. If the terminal member is not securely anchored to the other components of the disposable electrode, it may pull out when force is applied to disconnect the terminal member from the female portion of the snap fastener.

To avoid this problem, a two-piece terminal member is typically used comprising a so-called "stud and eyelet" arrangement. The stud comprises a flat circular portion and a pin-like member extending perpendicularly therefrom. The stud is inserted into an eyelet comprising a hollow knob having a circular base. The adhesive tape or stiffening piece used to reinforce the adhesive tape is sandwiched between the stud and the eyelet. After the stud is inserted into the eyelet, the eyelet is crimped at its neck to ensure good electrical contact between the stud and eyelet and securely anchor the adhesive tape or stiffening piece. Alternatively, the stud can be friction fitted within the eyelet without crimping.

The two-piece terminal member as described above suffers from a number of disadvantages including potential corrosion problems if the stud and eyelet are made from dissimilar metals, electrical resistance between the stud and eyelet, and increased difficulty and cost of manufacturing.

Because of the disadvantages associated with the two-piece terminal member, particularly its high cost, a number of attempts have been made to solve the anchoring problems encountered with one-piece terminal members so that the latter might be more suitable for disposable bioelectrodes.

U.S. Patent No. 3,841,312 describes a retaining ring which fits over the projecting portion of the terminal member to mechanically secure the adhesive tape to the flat base portion of the terminal member.

U.S. Patent No. 3,993,049 discloses a bioelectrode having a one-piece terminal member which is mechanically attached to the other layers of the electrode by a swaged stiffening member. U.S. Patent No. 4,029,086 describes a disposable bioelectrode having a one-piece terminal member in which the projecting portion thereof contains a ridge over which a washer is snapped to secure the terminal member to the adhesive pad. U.S. Patent No. 4,117,846 describes a similar method utilizing a pair of washers to secure the terminal member to the adhesive pad.

In general, the prior art methods of anchoring the one-piece terminal member to the other components of the electrodes have involved a friction-fit washer or retaining ring which is mechanically biased against the stem of the knob-like projection of the terminal member. Although such methods of anchoring generally produce satisfactory anchoring of the terminal member to the electrode, they complicate the manufacture of the electrode and increase its cost.

The biomedical electrode of the present invention overcomes the disadvantages of the prior biomedical electrodes by securely anchoring the one-piece terminal member within the electrode without the necessity of washers or other retaining means that are mechanically biased against the projecting portion of the terminal member. This dramatically simplifies the method of manufacture of the electrode without compromising its mechanical integrity. The use of a metal layer in conjunction with the anchoring means improves the electrical performance of the electrode and permits the use of a wide variety of ionically conductive mediums including conductive adhesives.

Summary of the invention

A biomedical electrode according to the present invention is defined in the accompanying Claim 1. The

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pre-characterizing part of the claim is already known from the aforementioned U.S. Patent No. 4,273,135. The characterizing part of Claim 1 defines the improvements that have been made (a) to securely anchor the terminal in position without the need for a two piece stud and eyelet terminal and (b) to facilitate production procedure.

- 5 The invention also relates to a method of making a biomedical electrode, said method being defined in the accompanying Claim 7.

The terms ionically conductive as used herein to describe the layer mean the layer is electrically conductive due to the inclusion of sufficient amounts of ionic substances as well known in the art. The term retainer as used herein to describe the retainer sheet means the sheet has sufficient structural integrity to 10 withstand the forces encountered in normal use without the need of washers or other retaining means that are mechanically biased against the post. The retainer sheet resists tearing, stretching and the like to positionally confine the terminal member within the electrode. In use, the post of the terminal member is connected to the lead wire of the electromedical device and the conductive layer is held in contact with the skin. As the patient moves around or when the lead wire is disconnected from the terminal member, a force 15 is applied to the terminal member. This force tends to separate the terminal member from the remainder of the electrode. The retainer sheet resists this force. It does not, for example, stretch sufficiently to allow the base to pass through the aperture in the retainer sheet. Instead, the electrode separates from the skin or the mechanical attachment of the lead wire to the terminal member is broken before the terminal member is disassociated from the remainder of the electrode.

- 20 The preferred embodiment of the disposable biomedical electrode of the present invention further comprises an electrically-conductive metal or metallized layer disposed between the retainer sheet and the upper surface of the base and also extending beyond the periphery of the base between the retainer sheet and a substantial portion of the conductive layer. It is especially preferred that this metal or metallized layer be coextensive with the retainer sheet and pre-attached thereto by vapor-deposition or other conventional 25 coating techniques prior to assembly of the electrode. The presence of the metal or metallized layer improves conduction of electrical impulses from the skin to the terminal member.

The preferred embodiment of the disposable biomedical electrode of the invention also comprises a medical tape comprising of a backing and a pressure-sensitive adhesive coating on at least one surface thereof, the tape having an aperture therein dimensioned to receive said post. The adhesive coated surface 30 of the tape contacts the retaining sheet and extends beyond the periphery of the retaining sheet and the ionically-conductive layer to assist in securing the electrode to the skin. This may be necessary when a cohesive conductive gel that does not exhibit sufficient adhesiveness is used as the conductive layer. In the preferred embodiment, the ionically conductive layer is comprised of a pressure-sensitive, electrically conductive adhesive.

- 35 Protective release liners are also included in the disposable electrode to protect the conductive layer and the adhesive-coated surface of the tape prior to application of the electrode to the skin.

Furthermore, in the preferred embodiment of the electrode, electric current is conducted simultaneously through the conductive layer to the terminal member and through the metal or metallized layer to the terminal member. This increases the overall electrical sensitivity of the electrode and reduces 40 the criticality of the nature of the conductive layer utilized. More particularly, since a large portion of the electric current travels a significant portion of the distance from the underlying skin to the terminal member through a near-perfect conductor, i.e., the metal or metallized layer, the overall electric noise within the electrode is significantly reduced.

- 45 Brief description of the drawings

Other advantages of the invention will become apparent from the following drawings wherein like numerals refer to like parts, the accompanying description and the appended claims.

Figure 1 is a top view of a strip of biomedical electrodes of the present invention made according to the method of the present invention.

- 50 Figure 2 is a cross-sectional view of one of electrodes shown in Figure 1, taken along the line 2—2 of Figure 1.

Figure 3 is a schematic representation of a method of manufacturing the strip of biomedical electrodes of Figure 1.

- 55 Figure 4 is a bottom view of a strip of biomedical electrodes of the present invention being formed according to the method represented in Figure 3.

Figure 5 is an exploded, cross-sectional view taken along 5—5 of Figure 4.

Description

Referring now generally to the drawings and in particular to Figures 1 and 2, there is shown a strip 10 of 60 biomedical electrodes 12 of the present invention made according to the method of the present invention. As shown, the electrode 12 generally comprises an electrical terminal member 14, a conformable, ionically conductive layer 16, and a retainer sheet 18. The terminal member 14 comprises a base 20 having generally coplaner upper and lower surfaces 22 and 24, respectively, and an upstanding post 26 integral with the upper surface 22 of the base 20. The post 26 is adapted for connection with a lead wire, not shown, which, in turn, is attached to the electromedical apparatus. The terminal member 14 is preferably comprised of 65

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metal or is provided with a metallized outer layer, but it can also comprise other materials such as conductive carbon. The conductive layer 16 underlies and is in physical and electrical contact with the lower surface 24 of the base 20 and extends outward from the periphery thereof. The surface of the conductive layer 16 opposite that contacting the terminal member 14 is supplied to the skin of the patient. A

- 5 protective release liner 17 overlies the exposed surface of conductive layer 16 prior to application to the patient.

The terminal member 14 is securely retained within the electrode 12 by the retainer 18. The retainer sheet 18 is comprised of an upper major surface 19 and a lower major surface 21 bound together by edge surfaces 23. The retainer sheet 18 has an aperture 28 there through spaced apart from the edge surfaces 23 10 and dimensioned to receive and to surround the post 26. The aperture 28 is preferably larger in diameter than the largest diameter of post 26 of the terminal member 14. The retainer sheet 18 overlies a substantial portion of the upper surface 22 of the base 20 and extends beyond the periphery of base 20 to overlie a substantial portion of layer 16.

Electrode 12 further comprises an electrically-conductive metal or metallized layer 30 which is 15 preferably formed from the same metal as that forming the terminal member. The metal layer 30 has an aperture there through that is dimensioned to receive the post 26 and is preferably larger in diameter than the largest diameter of the post 26. Metal layer 30 is disposed between the retainer sheet 18 and the upper surface 22 of the base 20 and extends outward beyond the periphery of base 20 between the retainer sheet 18 and the conductive layer 16. Preferably metal layer 30 is coextensive with retainer sheet 18 and 20 pre-attached thereto by vapor deposition or other conventional means. The metal layer 30 causes electrical impulses picked up on the mammalian skin to be conducted simultaneously through the ionically conductive layer 16 and through the metal layer 30 to the terminal member 14.

A number of suitable materials may be chosen for the metal layer 30. For example, the metal layer 30 can be comprised of a metal foil, e.g., silver or tin foil, or metal flakes. As noted above, the metal layer 30 is 25 preferably directly applied to the retainer sheet 18 by conventional coating, printing or laminating techniques or the like. By utilizing the same metal for the metal layer 30 and the terminal member 14, the potential for corrosion between the interface of the metal layer 30 and the terminal member 14 is essentially eliminated.

A number of materials can be used for the retainer sheet 18. In the preferred embodiment, where 30 retainer sheet 18 and metal layer 30 are preattached to each other, the retainer sheet 18 is comprised of a gravure printed, silver/silver chloride treated, polyester film. The polyester film is a dielectric material that can insulate the remainder of the electrode 12 from stray electrical signals that could otherwise be picked up from the surroundings including static charges from nearby clothing, bedding, or the like. Other materials will work. For example, various polyethylene, polypropylene and vinyl films can be used. Another 35 suitable material is number 57 EDP "facer only" paper available from Green Bay Packaging Inc., P.O. Box 1107, Green Bay, Wisconsin 54305.

Similarly, a number of materials can be used for the ionically conductive layer 16. In the preferred embodiment, the layer 16 is comprised of a pressure-sensitive, conductive adhesive. Certain cohesive conductive gels will also work. Suitable gels are disclosed in U.S. Patent No. 4,377,170 which is hereby 40 incorporated by reference. If a non-adhesive, cohesive conductive gel is used for the layer 16, the layer 16 would have to be otherwise adhered to the retainer sheet 18. The layer 16 is satisfactorily adhered to the retainer sheet 18 by peripherally taping the layer 16 to the retainer sheet 18 with a suitable medical tape as described more fully below.

The use of the retainer sheet 18 greatly simplifies the construction of the electrode 12 without 45 compromising the integrity of the electrical connection of the terminal member 14 with the ionically conductive layer 16. As taught by the present invention, the retainer sheet 18 intimately contacts the metal layer 30 and the base 20 of the terminal member 14 without the need for washers, retaining rings or the like which are mechanically biased against the post 26. There is no dissimilar material interposed between the metal layer 30 and the base 20 that could give rise to electrical noise. This is made possible by the inclusion 50 of the retainer sheet 18. At the same time, the retainer sheet 18 securely holds the terminal member 14 within the electrode 12; the terminal member 14 cannot be easily pulled out in use when adapted to the lead wire.

The biomedical electrode 12 includes a medical tape 32 having an aperture 33 there through that is dimensional to receive the post 26 and is preferably larger in diameter than the largest diameter of the post 55 26. The medical tape 32 is adhered to the upper major surface 19 of the retainer sheet 18 and extends outward from the periphery thereof to assist in adhering the electrode 12 to the skin. The medical tape 32 comprises a backing 35 and a suitable pressure sensitive adhesive 36 on the surface contacting the upper surface 19 of the retainer sheet 18 and the skin. A suitable medical tape is available from Minnesota Mining and Manufacturing Company, 3M Center, St. Paul, Minnesota 55144 under the trademark "Micropore"®.

60 The adhesive 36 of the medical tape 32 extending beyond the periphery of the retainer sheet 18 is adhered to a silicone-coated release liner 38 as is well known in the art. The underside of the release liner 38, in turn, is adhered to a suitable protective sheet 40 comprising a backing 42 and a pressure-sensitive adhesive 44. Protective sheet 40 is present to cover the apertures formed in the release liner 38 during the manufacture of the electrodes 12 as described below and contact protective release liner 17 over ionically 65 conductive layer 16. Protective sheet 40 assists in the removal of the layer 16 from liner 17.

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A method for producing the biomedical electrode 12 will next be described in relation to Figures 3, 4 and 5. Referring primarily to Figure 3, there is shown in schematic representation, a method of continuously manufacturing the strip 10 of biomedical electrodes 12 with the use of automated equipment. As shown, the release liner 38 is stored on a roll 45. When the automated equipment is energized, the 5 release liner 38 is pulled off the roll 45 by tension-unwind rollers 47. The release liner 38 is guided towards the rollers 47 by constant tension, unwind rollers 46.

From the rollers 47, the release liner 38 is pulled through conventional die-cutting rollers 48. The die-cutting rollers 48 die-cut the release liner 38 to form rectangularly shaped pieces 50 and apertures 52 in the release liner 38. At the same time, longitudinal cut 54 is made in the release liner 38. This is best shown 10 in Figure 4 and Figure 5. The rectangularly shaped piece 50 is removed from the release liner 39 by a kicker spring 57 and a vacuum 58. The release liner 38 is guided past the vacuum 58 by rollers 60.

Once the apertures 52 are formed in the release liner 38, the medical tape 32 is adhered to the release liner 38 by laminating rollers 62. As noted earlier, the medical tape can be "Micropore"® brand medical tape. A suitable width for the medical tape 32 and for the release liner 38 is 3-1/2 inches (8.89 cm). A suitable 15 adhesive weight for the medical tape 32 is 6 to 12 grains.

The medical tape 32 is stored on a roll 64. When the automated equipment is energized, the medical tape 32 is pulled and guided towards the laminating rollers 62 by rollers 66.

After the medical tape 32 is laminated to the release liner 38, the outlines of the individual electrodes 12 are formed on the medical tape 32 by conventional die-cutting rollers 68. The die-cutting rollers 68 make 20 controlled-depth cuts 70 in the medical tape 32 and remove indentations 72 in medical tape 32 and in release liner 38 to form tabs 74. This is best shown in Figure 4. Through the use of controlled-depth cutting with the rollers 68, the cuts 70 in the medical tape 32 are made without cutting the release liner 38. The tabs 74 facilitate removal of the individual electrodes 12 from release liner 38 and will be later explained in conjunction with the use of the electrodes 12.

25 After the individual electrodes 12 are outlined on the medical tape 32, the strip 10 is pulled and guided by rollers 76 to die-cutting and laminating rollers 78. The rollers 78 laminate the retainer sheets 18 to the medical tape 32. Retainer sheets 18 are cut from roll 80. The sheeting material is pulled from roll 80 by a roller 82 and guided to the die-cutting and laminating rollers 78. The upper roller 78 transversely cuts the sheeting material into lengths forming retainer sheets 18 and carries the sheets 18 down to the lower roller 78 where the individual sheets 18 are adhered to the medical tape 32 through the apertures 52 in the release 30 liner 38. In the preferred embodiment, the electrically conductive metal layer 30 is already adhered to the sheeting material on the roll 80. This can be accomplished by coating, printing or laminating the sheeting material with the metal or metallized layer 30 as already described. As the sheeting material is unrolled from the roll 80, metal layer 30 is cut with the retainer sheet 18, and the combination is adhered to the 35 medical tape 32.

From the foregoing, it is clear that the inclusion of the metal layer 30 can be made optional. Exclusion of the metal layer 30 will generally result in higher electrode impedances depending upon the exact conductive adhesive 16 employed, but satisfactory performance can still be achieved by well-known techniques.

40 Next, the aperture 28 in the retainer sheet 18 is formed by die-cutting rollers 84. The strip 10 is pulled and guided in the rollers 84 by rollers 86. Die-cutting rollers 84 extend the aperture 28 in retainer sheet 18 on through the medical tape 32 to form the aperture 33. This is best seen in Figure 4 and Figure 5. The strip 10 is pulled from the rollers 84 and guided on through the equipment by rollers 88. At rollers 88, loose material resulting from the extension of the aperture 28 through the medical tape 32 to form the aperture 33 45 is removed by the vacuum 89.

The strip 10 is fed to the rollers 90 by the rollers 91. At rollers 90, the terminal members are placed within the apertures 28 and 33 by a vacuum placement system 92 within the upper roller 90. As described earlier, when the terminal members 14 are placed within the apertures 28 and 33, the upper major surface 22 of the base 20 is contacted with the lower surface of metal layer 30. The terminal members 14 are fed to 50 the vacuum placement system 92 by a vibratory feeder 94.

After the terminal members 14 are properly located, the strip 10 is again pulled and guided to the next operation by a pair of rollers 96. The next operation comprises the addition of the ionically conductive layer 16. The sheeting material from which the layers 16 are cut is stored on a roll 98. One major surface of the layer 16 is covered with a silicone-coated protective release liner 17 similar to the release liner 38. The release liner 17 is shown in Figure 2 and in Figure 5. It serves two purposes. Firstly, it prevents the layer 16 from sticking to itself on the roll 98. This is especially important when the layer 16 is comprised of the pressure-sensitive, conductive adhesive described earlier. Additionally, the release liner 17 protects the layer 16 after the electrode 12 is fully manufactured and until the electrode 12 is applied to the skin.

60 The layer 16 and the release liner 17 are guided to die-cutting and laminating rollers 99 and 100 by a guide 101. The roller 100 can have an internal vacuum system that holds layer 16 and release liner 17 against the roller 100 until cut to approximately the size and shape of the aperture 52 in the release liner 38. The rollers 99 and 100 also adhere the lower major surface of the metal layer 30 to the upper surface of the conductive adhesive layer 16 through the aperture 52 in the release liner 38.

65 The release liner 17 is secured to the release liner 38 by the protective sheet 40 from a roll 102. As

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described earlier, the protective sheet 40 is comprised of the suitable backing material 42 and the pressure-sensitive adhesive 44. It is shown in Figure 2 and Figure 5.

Finally, the strip 10 is guided to die-cutting rollers 104 by rollers 106 where it is cut into suitable lengths of strips 10 by the die-cutting rollers 104. At the same time, the individual electrodes 12 can be made separable by perforating the release liner 38 along each of the cuts 70 in the medical tape 32. The result is the strip 10 of biomedical electrodes 12 shown in Figure 1.

The strips 10 of the electrodes 12 are sealed in suitable protective, clean packages prior to shipment to the end users. The electrodes 12 are used by pulling the individual electrodes 12 away from the release liner 38 with the aid of the tabs 74 and applying the electrodes 12 to the patient as prescribed by qualified medical personnel. The materials chosen for the medical tape 32, the release liners 38 and 17 and the layer 16 are such that the bond between medical tape 32 and the release liner 38 and the bond between the conductive layer 16 and the release liner 17 are broken to allow the electrode 12 to be peeled away from the rest of the strip 10 so that the electrode 12 can be applied to the patient. These material characteristics are conventional and well known in the art.

Using the above-described method, five electrodes of the present invention were made to include the following:

Example 1

"Scotchpar"® brand polyester film, available from Minnesota Mining and Manufacturing Company, was adhered to six-grain, "Micropore"® medical tape. The polyester film included a 5×10^{-4} centimeters thick layer of #5005 silver composition ink available from E. I. Du Pont De Nemours, Company, Inc., 1007 Market Street, Wilmington, DE 19898. An aperture having a diameter of .41 centimeters was die cut through the center of the medical tape and polyester film lamination. A terminal member having a .41 centimeters diameter post and a .86 centimeters diameter base was located within the aperture. The lower surface of the base of the terminal member and the silver coated surface of the polyester film were covered with Lectron™ III, Chloride-1 conductive gel available from Pharmaceutical Innovations, Inc. Newark, New Jersey 07114.

The five electrodes were tested to determine their resistance to the terminal members being pulled out or otherwise separated from the remainder of the respective electrodes using an "Instron"® brand load-elongation testing instrument, Model 1122, available from the Instron Corporation, 2500 Washington Street, Canton, MA 02021. The electrodes were, one at a time, adhered to an immovable surface preprepared with 9 mm, double-coated, paper tape, #401, available from Minnesota Mining and Manufacturing Company, 3M Center, Saint Paul, MN 55144. The medical tape and the conductive gel used were adhered to the paper tape which, in turn, was adhered to a stainless steel plate. The stainless steel plate was rigidly attached to the testing instrument. The purpose of the paper tape was to insure that the medical tape and the conductive gel used did not separate from the stainless steel plate when force was applied to the terminal member.

Next, the post of the terminal member was grasped by a jaw of the testing instrument and pulled in an upward direction generally perpendicular to the plane of the electrode until the terminal member pulled out or otherwise separated from the rest of the electrode. For this test, the testing instrument was set at 100 mm per minute crosshead elongation speed.

The test results are recorded in Table 1. Also in Table 1 is recorded the results of separating the terminal members of five electrodes made the same as the five of Example 1 except that the polyester film and silver composition link were eliminated. Also in Table 1, are the results of subjecting commercially available monitoring electrodes to the same test procedure. In each case, five electrodes were tested. In each case, the mean separation force in Newtons (pounds) is recorded.

TABLE 1

		Mean terminal member separation force exhibited in Newtons (pounds)
	Electrode	
	Example 1 electrodes	86 (19.3)
55	Example 1 electrodes minus polyester film	21 (4.7)
	"Red Dot" brand monitoring electrodes #2249	45 (10.2)
60	"AMI" brand monitoring electrodes #1501-003	49 (11.1)
	"CON-MED" monitoring electrodes #934	25 (5.7)

In Table 1, the Red Dot® electrodes are available from Minnesota Mining and Manufacturing Company, 3M Center, Saint Paul, MN 55144. The AMI electrodes are available from Andover Medical Incorporated,

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Lowell, MA 01852. The CON-MED® electrodes are available from Consolidated Medical Equipment, Inc., 10 Hopper Street, Utica, NY 13501.

Claims

- 5 1. A biomedical electrode (12) comprising:
 - a. an electrical terminal member (14) comprising a base (20) having upper and lower surfaces (22, 24) and a post (26) integral with said upper surface (22) of said base (20) and extending therefrom, said post presenting an exposed surface adapted for direct physical and for electrical connection to a lead wire of an electromedical device;
 - b. an ionically conductive layer (16) in direct physical and electrical contact with the entire lower surface (24) of said base (20) and extending peripherally beyond said base; and
 - c. a retainer sheet (18) having upper (19) and lower (21) major surfaces bound together by an edge surface (23) and having an aperture therethrough surrounding the post, the aperture being spaced apart from said edge surface, the lower surface (21) of the retainer sheet (18) contacting the upper surface (22) of said base (20) and contacting also the ionically conductive layer (16) extending peripherally beyond the base (20) to positionally confine said electrical terminal member (14) between said retainer sheet (18) and said ionically conductive layer (16); characterized by:
 - d. a medical tape (32) comprising a backing (35) and a pressure sensitive adhesive (36) coating on at least one major surface thereof, said tape having an aperture (33) therethrough dimensioned to receive said post (26), a portion of said adhesive-coated surface being adhered to said upper surface (19) of said retainer sheet (18) and the remaining portion of said adhesive coated surface extending beyond the peripheral edges of said retainer sheet (18) and said ionically conductive layer (16) to assist in securing said electrode to skin;
 - e. a first release liner (17) having a surface area and shape as large as the lower surface area of the ionically conductive layer (16) and adhered to said lower surface of the ionically conductive layer;
 - f. a second release liner (38) adhered to the portion of the adhesive coated surface of said medical tape (32) which extends beyond the periphery of said retainer sheet (18) and said ionically conductive layer (16), said second release liner (38) having an aperture (52) therethrough accommodating the first release liner (17); and
 - g. a protective sheet (40) adhered to the underface of first liner (17) opposite said ionically conductive layer (16) and adhered to said second release liner (38) opposite said medical tape (32).
- 25 2. An electrode according to Claim 1 wherein the ionically conductive layer (16) comprises a pressure-sensitive, electrically-conductive adhesive.
- 30 3. An electrode according to Claim 2 further comprising an electrically-conductive metal or metallized layer (30) disposed between said retainer sheet (18) and said upper surface (22) of said base (20) in contact with said base (20) and extending outward from the periphery of said base (20) between said retainer sheet (18) and a substantial portion of said electrically-conductive adhesive (16).
- 35 4. The electrode (12) according to Claim 3 wherein said terminal member (14) comprises a metal or a metallized member and wherein said metal or metallized layer (30) comprises the same metal as that comprising said base (20) of said terminal member (14) which said layer (30) contacts.
- 40 5. An electrode according to any one of Claims 1 to 4, said retainer sheet (18) being of a polyester material.
- 45 6. An electrode according to Claim 3 wherein the metal or metallized layer (30) is essentially of silver.
7. A method of manufacturing biomedical electrodes comprising the steps of:
 - a. cutting apertures (52) at predetermined locations along the length of a first release liner (38);
 - b. laminating a medical tape (32) comprising a backing (35) and a pressure-sensitive adhesive (36) coating on at least one major surface thereof whereby the pressure sensitive adhesive of said tape is adhered to the release liner (38);
 - 50 c. cutting said medical tape (32) transversely between each of said apertures (52);
 - d. laminating a series of retainer sheets (18) having upper and lower major surfaces (19, 21) bound together by an edge surface (23) to said medical tape (32) through each of said apertures (52) in said first release liner whereby said retainer sheets (18) are adhered through said apertures (52) to said pressure sensitive adhesive of said medical tape (32);
 - e. cutting an aperture (28) through said retainer sheets (18) and on through said medical tape (32);
 - 55 f. locating an electrical terminal member (14) comprising a base (20) having upper and lower major surfaces (22, 24) and an upstanding post (26) integral with said upper major surface (22) of said base (20) in each aperture (28) in each retainer sheet (18) and in the medical tape (32) by extending said post (26) of said terminal member through said aperture (28) in the retainer sheet (18) until said upper major surface (22) of said base contacts the lower surface (21) of said retainer sheet (18);
 - 60 g. laminating an ionically conductive layer (16) to the lower surface (24) of said each base (20) and the lower surface (21) of each retainer sheet (18);
 - h. laminating a second release liner (17) to said ionically conductive layers (16) opposite said base (20) and said retainer sheets (18);
 - 65 i. laminating a protective sheet (40), comprising a pressure-sensitive adhesive (44) adhered to a

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backing (42), to said first release liner (38) opposite said medical tape (32) and to said second release liners (17) opposite said ionically conductive layers (16) whereby each of said second release liners (17) is secured to said first release liner (38); and

- 5 j. cutting said first release liner (38) and said protective sheet (40) transversely at predetermined locations along the length of said first release liner (38) and protective sheet (40) to form a strip (10) containing a multiplicity of electrodes (12) thereon.

8. The method according to Claim 7 wherein said ionically conductive layer (16) comprises a pressure-sensitive, electrically-conductive adhesive.

9. The method according to Claim 8 further comprising the step of directly applying an electrically-conductive metal or metallized layer (30) to said lower surface (21) of said sheet (18) whereby said upper major surface (22) of each base (20) contacts said metal or metallized layer (30).

10. The method according to Claim 9 wherein said terminal member (14) comprises a metal or a metallized member and wherein said metal or metallized layer (30) comprises the same metal as that comprising said base (20) of said terminal member (14) which said layer contacts (30).

15 Patentansprüche

1. Biomedizinische Elektrode (12) mit

a. einem elektrischen Anschlußglied (14), das einen Basisteil (20) mit einer oberen und einer unteren

20 Fläche (22, 24) und einen Pfosten (26) aufweist, der mit der oberen Fläche (22) des Basisteils (20) einstückig ist und sich von ihr erstreckt und eine freiliegende Fläche besitzt, die für eine direkte physische und elektrische Verbindung mit einem Zuleitungsdräht einer elektromedizinischen Vorrichtung geeignet ist;

b. einer ionenleitfähigen Schicht (16), die mit der ganzen unteren Fläche (24) des Basisteils (20) in direkter physischer und elektrischer Verbindung steht und sich in der Umfangsrichtung über den Basisteil 25 hinaus erstreckt; und

c. einem Halteblatt (18), das eine obere (19) und eine untere (21) Breitseitenfläche besitzt, die durch eine Randfläche (23) miteinander verbunden und von einer den Pfosten umgebenden Ausnehmung durchsetzt sind, wobei die untere Fläche (21) des Halteblattes (18) die obere Fläche (22) des Basisteils (20) berührt und auch die sich in der Umfangsrichtung über den Basisteil (20) hinaus erstreckende ionenleitfähige Schicht (16) berührt, so daß das elektrische Anschlußglied (14) zwischen dem Halteblatt 30 (18) und der ionenleitfähigen Schicht (16) gehalten wird; gekennzeichnet durch:

d. ein medizinisches Band (32), das einen Rücken (35) und auf mindestens einer Breitseitenfläche des Rückens einen Überzug aus einem Haftkleber (36) besitzt und das von einer zur Aufnahme des Pfostens (26) bermessenen Ausnehmung (33) durchsetzt ist, wobei ein Teil der klebstoffüberzogenen Fläche an der 35 oberen Fläche (19) des Halteblattes (18) angeklebt ist und der übrige Teil der klebstoffüberzogenen Fläche sich über die Umfangsränder des Halteblattes (18) und der ionenleitfähigen Schicht (16) hinaus erstreckt, um das Festlegen der Elektrode an Haut zu unterstützen;

e. eine erste Antihaftauflage (17), die denselben Flächeninhalt und dieselbe Form hat wie die untere Fläche der ionenleitfähigen Schicht (16) und an der unteren Fläche der ionenleitfähigen Schicht angeklebt 40 ist;

f. eine zweite Antihaftauflage (38), die an dem sich über den Umfang des Halteblattes (18) hinaus erstreckenden Teil der klebstoffüberzogenen Fläche des medizinischen Bandes (32) und der ionenleitfähigen Schicht (16) angeklebt ist und die von einer die erste Antihaftauflage (17) aufnehmenden Ausnehmung (52) durchsetzt ist; und

45 g. eine Schutzblatt (40) das gegenüber der ionenleitfähigen Schicht (16) an der unteren Fläche der ersten Auflage (17) und gegenüber dem medizinischen Band (32) an der zweiten Antihaftauflage (38) angeklebt ist.

2. Elektrode nach Anspruch 1, dadurch gekennzeichnet, daß die ionenleitfähige Schicht (16) mindestens teilweise aus einem elektrisch leitfähigen Haftkleber besteht.

50 3. Elektrode nach Anspruch 2 mit einer elektrisch leitenden, metallischen oder metallisierten Schicht (30), die zwischen dem Halteblatt (18) und der oberen Fläche (22) des Basisteils (20) angeordnet ist und mit dem Basisteil (20) in Berührung steht und sich zwischen dem Halteblatt (18) und einem beträchtlichen Teil des elektrisch leitfähigen Klebers (16) vom Umfang des Basisteils (20) auswärts erstreckt.

55 4. Elektrode (12) nach Anspruch 3, dadurch gekennzeichnet, daß das Anschlußglied (14) einen metallischen oder metallisierten Teil besitzt und die metallische oder metallisierte Schicht (30) mindestens zum Teil aus einem Metall besteht, das auch in dem von der Schicht (30) berührten Basisteil (20) des Anschlußgliedes (14) vorhanden ist.

5. Elektrode nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß das Halteblatt (18) aus Polyester besteht.

60 6. Elektrode nach Anspruch 3, dadurch gekennzeichnet, daß die metallische oder metallisierte Schicht (30) im wesentlichen aus Silber besteht.

7. Verfahren zum Herstellen von biomedizinischen Elektroden mit folgenden Schritten:

a. aus einer ersten Antihaftauflage (38) werden an vorherbestimmten, über die Länge der Auflage verteilten Stellen Ausnehmungen (52) ausgeschnitten;

65 b. auf mindestens eine Breitseitenfläche der Antihaftauflage (38) wird ein medizinisches Band (32), das

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einen Rücken und auf mindestens einer Breitseitenfläche einen Haftkleber (36) besitzt, derart aufkaschiert, daß der Haftkleber des Bandes mit der Antihaftauflage (38) verklebt wird;

- c. das medizinische Band (32) wird zwischen jeweils zweien der Ausnehmungen (52) quer durchgeschnitten;
 - 5 d. auf das medizinische Band (32) wird durch jede der Ausnehmungen (52) in der ersten Antihaftauflage hindurch eine Reihe von Halteblättern (18), die eine obere und eine untere Fläche (19, 21) besitzen, die durch eine Randfläche (32) miteinander verbunden sind, derart aufkaschiert, daß die Halteblätter (18) durch die Ausnehmungen (52) hindurch mit dem Haftkleber des medizinischen Bandes (32) verklebt werden;
 - 10 e. es wird eine die Halteblätter (18) und das medizinische Band (32) durchsetzende Ausnehmung (28) ausgeschnitten;
 - f. in jeder Ausnehmung (28) jedes Halteblattes (18) und des medizinischen Bandes wird ein elektrisches Anschlußglied (14) angeordnet, das einen Basisteil (20) mit einer oberen und einer unteren Breitseitenfläche (22, 24) und einen mit der oberen Breitseitenfläche (22) des Basisteils (20) einstückigen,
 - 15 f. aufwärtsgerichteten Pfosten (26) aufweist, der derart durch die Ausnehmung (28) in dem Halteblatt (18) hindurchgeführt wird, daß die obere Breitseitenfläche (22) des Basisteils die untere Fläche (21) des Halteblattes (18) berührt;
 - g. auf die untere Fläche (24) des Basisteils (20) und die untere Fläche (21) jedes Halteblattes (18) wird eine ionenleitfähige Schicht (16) aufkaschiert;
 - 20 h. gegenüber dem Basisteil (20) und den Halteblät (18) wird auf die ionenleitfähigen Schichten (16) eine zweite Antihaftauflage (17) aufkaschiert;
 - i. auf die erste Antihaftauflage (38) wird gegenüber dem medizinischen Band (32) und auf die zweite Antihaftauflagen (17) wird gegenüber den ionenleitfähigen Schichten (16) ein Schutzblatt (40), das einen an einem Rücken (42) klebenden Haftkleber (44) aufweist, derart aufkaschiert, daß jede der zweiten
 - 25 j. Antihaftauflagen (17) an der ersten Antihaftauflage (38) befestigt wird; und
 - j. die erste Antihaftauflage (38) und das Schutzblatt (40) werden an vorherbestimmten, über die Länge der ersten Antihaftauflage (38) und des Schutzblattes verteilten Stellen quer durchgeschnitten, so daß ein Streifen (10) erhalten wird, auf dem eine Vielzahl von Elektroden (12) vorgesehen sind.
8. Verfahren nach Anspruch 7, dadurch gekennzeichnet, daß die ionenleitfähige Schicht (16)
- 30 mindestens teilweise aus einem elektrisch leitfähigen Haftkleber besteht.
9. Verfahren nach Anspruch 8, in dem in einem weiteren Schritt auf die untere Fläche (21) des Blattes (18) eine elektrisch leitfähige, metallische oder metallisierte Schicht (30) direkt aufgetragen wird, so daß die obere Breitseitenfläche (22) jedes Basisteils (20) die metallische oder metallisierte Schicht (30) berührt.
10. Verfahren nach Anspruch 9, dadurch gekennzeichnet, daß das Anschlußglied (14) einen
- 35 metallischen oder metallisierten Teil besitzt und die metallische oder metallisierte Schicht (30) mindestens zum Teil aus einem Metall besteht, das auch in dem von der Schicht (30) berührten Basisteil (20) des Anschlußgliedes (14) vorhanden ist.

Revendications

- 40 1. Electrode biomédicale (12) comprenant:
 - a) une borne électrique (14) comportant une base (20), qui présente des surfaces supérieure et inférieure (22, 24), et un bossage (26) solidaire de ladite surface supérieure (22) de ladite base (20) et partant de celle-ci, ledit bossage présentant une surface découverte prévue pour le raccordement physique direct et pour la connexion électrique à un conducteur d'un dispositif électromédical;
 - b) une couche ioniquement conductrice (16) en contact physique et électrique direct avec toute la surface inférieure (24) de ladite base (20) et s'étendant périphériquement au-delà de ladite base; et
 - c) une feuille de retenue (18) présentant des surfaces principales supérieure (19) et inférieure (21) reliées ensemble par une surface de bord (23) et comportant une ouverture traversante qui entoure le bossage, l'ouverture étant espacée de ladite surface de bord, la surface inférieure (21) de la feuille de retenue (18) étant en contact avec la surface supérieure (22) de ladite base (20) et étant également en contact avec la couche ioniquement conductrice qui s'étend périphériquement au-delà de la base (20), de manière à emprisonner en position ladite borne électrique (14) entre ladite feuille de retenue et ladite couche ioniquement conductrice (16); caractérisée par:
- 45 55 d) un ruban médical (32) comprenant un support (35) et un revêtement adhésif sensible à la pression (36) sur au moins une surface principale de celui-ci, ledit ruban comportant une ouverture traversante (33) dimensionnée pour recevoir ledit bossage (26), une partie de ladite surface revêtue d'adhésif étant collée à ladite surface supérieure (19) de ladite feuille de retenue (18) et la partie restante de ladite surface revêtue d'adhésif s'étendant au-delà des bords périphériques de ladite feuille de retenue (18) et de ladite couche ioniquement conductrice (16) pour aider à fixer ladite électrode à la peau;
- 50 60 e) une première pellicule de décollement (17) ayant une surface et une forme aussi grandes que la surface inférieure de la couche ioniquement conductrice (16) et collée à ladite surface inférieure de la couche ioniquement conductrice;
- f) une deuxième pellicule de décollement (38) collée à la partie de la surface revêtue d'adhésif dudit ruban médical (32) qui s'étend au-delà de la périphérie de ladite feuille de retenue (18) et de ladite couche

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ioniquement conductrice (16), ladite deuxième pellicule de décollement (38) comportant une ouverture traversante (52) pour le logement de la première pellicule de décollement (17); et

g) une feuille de protection (40) collée à la face inférieure de la première pellicule (17), à l'opposé de ladite couche ioniquement conductrice (16), et collée à ladite deuxième pellicule de décollement (38) à l'opposé dudit ruban médical (32).

2. Electrode suivant la revendication 1, dans laquelle la couche ioniquement conductrice (16) comprend un adhésif sensible à la pression qui est électriquement conducteur.

3. Electrode suivant la revendication 2, comprenant en outre une couche (30) électriquement conductrice métallique ou métallisée, disposée entre ladite feuille de retenue (18) et ladite surface supérieure (22) de ladite base (20), en contact avec ladite base (20) et s'étendant vers l'extérieur par rapport à la périphérie de ladite base (20) entre ladite feuille de retenue (18) et une partie importante dudit adhésif électriquement conducteur (16).

4. Electrode (12) suivant la revendication 3, dans laquelle ladite borne (14) comprend une pièce métallique ou métallisée, et dans laquelle ladite couche métallique ou métallisée (30) comprend le même métal que celui qui constitue ladite base (30) de ladite borne (14) avec laquelle ladite couche (30) est en contact.

5. Electrode suivant l'une quelconque des revendications 1 à 4, ladite feuille de retenue (18) étant en polyester.

6. Electrode suivant la revendication 3, dans laquelle la couche métallique ou métallisée (30) est essentiellement en argent.

7. Procédé de fabrication d'électrodes biomédicales comprenant les opérations de:

a) découpe d'ouvertures (52) à des endroits prédéterminés sur la longueur d'une première pellicule de décollement (38);

b) stratification d'un ruban médical (32), comprenant un support (35) et un revêtement (36) d'adhésif sensible à la pression sur au moins une surface principale; de sorte que l'adhésif sensible à la pression dudit ruban est collé à la pellicule de décollement (38);

c) coupe dudit ruban médical (32) transversalement entre chacune desdites ouvertures (52);

d) superposition d'une série de feuilles de retenue (18) présentant des surfaces principales supérieure et inférieure (19, 21), réunies l'une à l'autre par une surface de bord (23), audit ruban médical (32) à travers

30 chacune desdites ouvertures (52) ménagées dans ladite première pellicule de décollement, de sorte que lesdites feuilles de retenue (18) sont liées à travers lesdites ouvertures (52) audit adhésif sensible à la pression dudit ruban médical (32);

e) découpe d'une ouverture (28) à travers lesdites feuilles de retenue (18) puis à travers ledit ruban médical (32);

35 f) mise en place d'une borne électrique (14) comportant une base (20), qui présente des surfaces principales supérieure et inférieure (22, 24), et un bossage vertical (26) solidaire de ladite surface principale supérieure (22) de ladite base (20), dans chaque ouverture (28) de chaque feuille de retenue et dans le ruban médical (32) par passage dudit bossage (26) de ladite borne à travers ladite ouverture (28) de la feuille de retenue (18) jusqu'à ce que ladite surface principale supérieure (22) de ladite base vienne en contact avec la surface inférieure (21) de ladite feuille de retenue (18);

g) superposition d'une couche ioniquement conductrice (16) à la surface inférieure (24) de chaque dite base (20) et à la surface inférieure (21) de chaque feuille de retenue (18);

h) stratification d'une deuxième pellicule de décollement (17) auxdites couches ioniquement conductrices (16) à l'opposé de ladite base (20) et desdites feuilles de retenue (18);

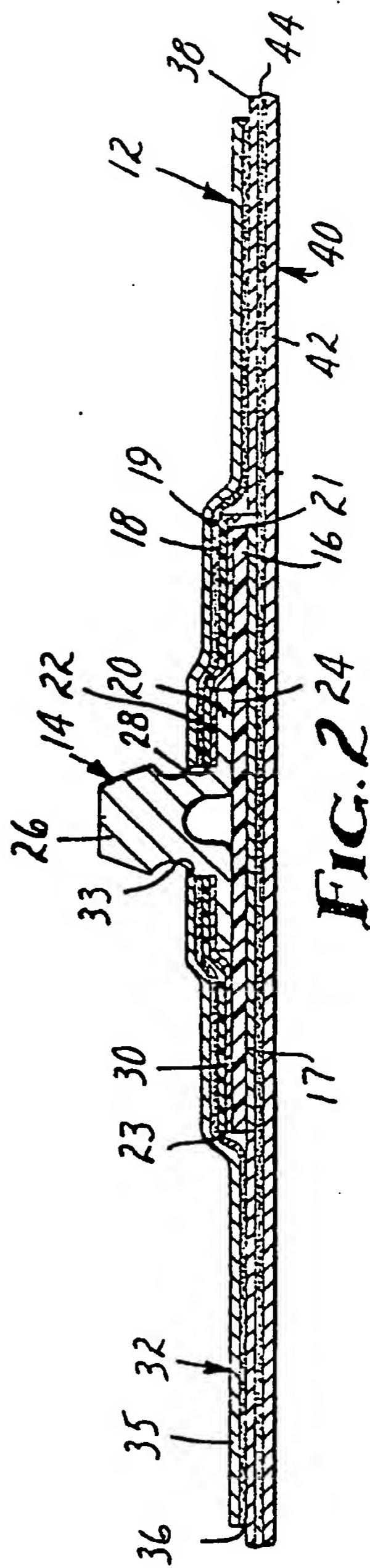
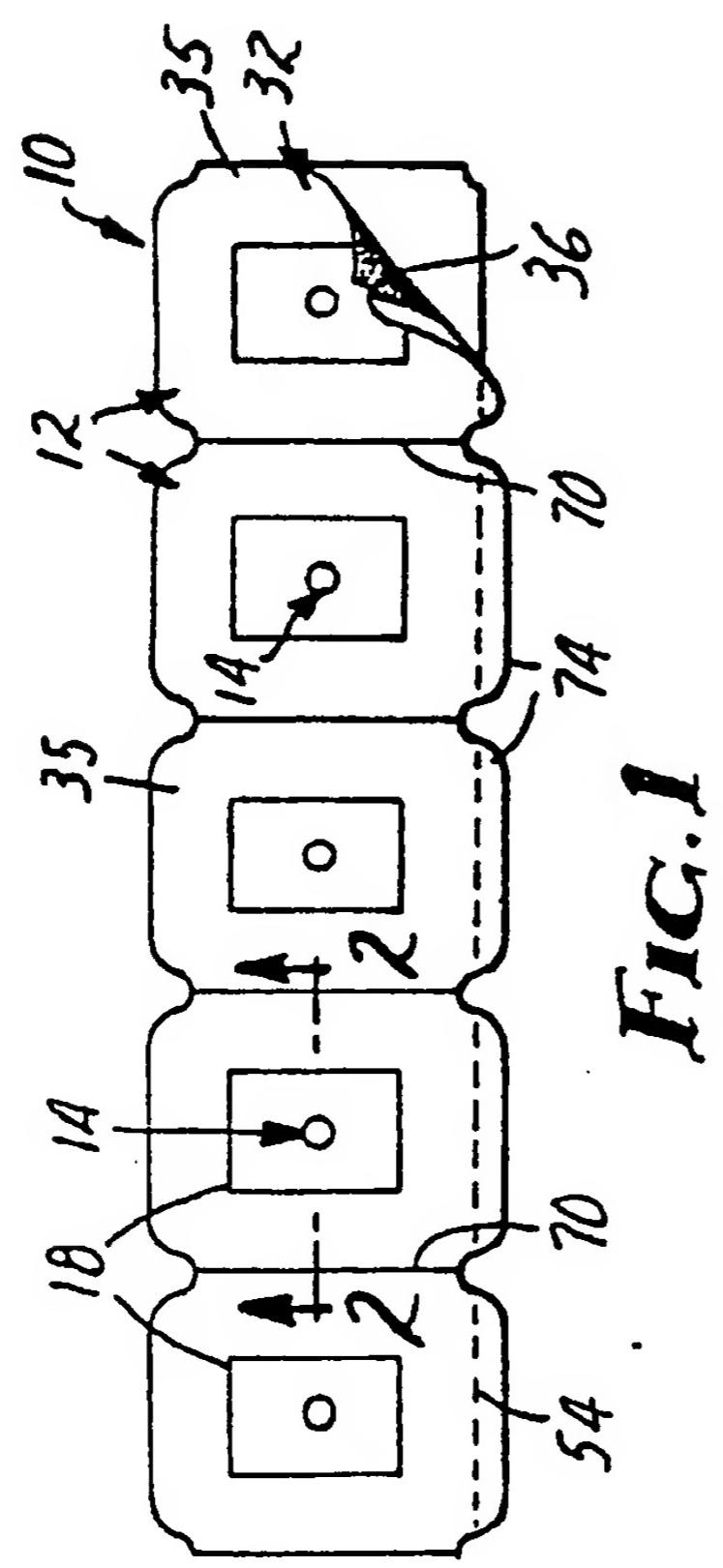
45 i) stratification d'une feuille de protection (40), comprenant un adhésif sensible à la pression (44) collé à un support (42), à ladite première pellicule de décollement (38), à l'opposé dudit ruban médical (32), et auxdites deuxièmes pellicules de décollement (17) à l'opposé desdites couches ioniquement conductrices (16), de sorte que chacune desdites deuxièmes pellicules de décollement (17) est fixée à ladite première pellicule de décollement (38); et

50 j) coupe de ladite première pellicule de décollement (38) et de ladite feuille de protection (40) transversalement, à des endroits prédéterminés sur la longueur de ladite première pellicule de décollement (38) et de la feuille de protection (40), pour former une bande (10) contenant une pluralité d'électrodes (12).

8. Procédé suivant la revendication 7, dans lequel ladite couche ioniquement conductrice (16) comprend un adhésif sensible à la pression, électriquement conducteur.

55 9. Procédé suivant la revendication 8, comprenant en outre l'opération d'application directe d'une couche (30) électriquement conductrice métallique ou métallisée à ladite surface inférieure (21) de ladite feuille (18), de sorte que ladite surface principale supérieure (22) de chaque base (20) est en contact avec ladite couche en métal ou métallisée (30).

10. Procédé suivant la revendication 9, dans lequel ladite borne (14) comprend une pièce métallique ou métallisée, et dans laquelle ladite couche métallique ou métallisée (30) comprend le même métal que celui qui constitue ladite base (20) de ladite borne (14) avec laquelle ladite couche (30) est en contact.



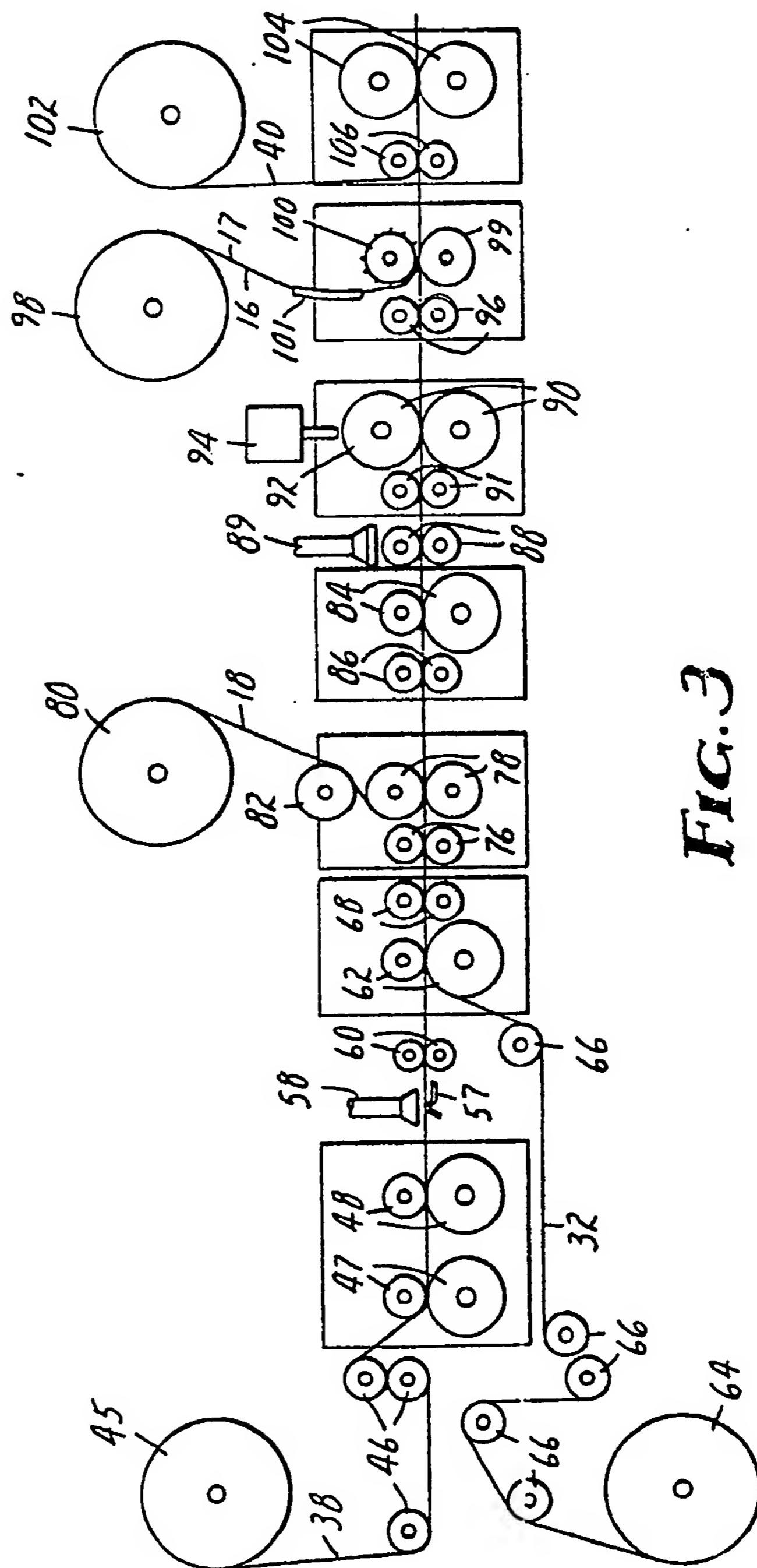


FIG. 3

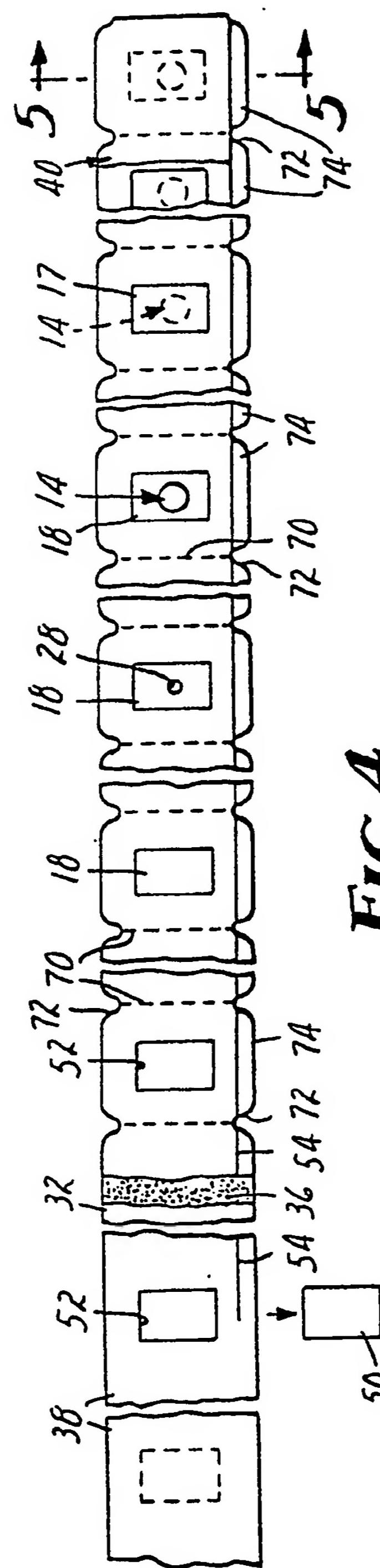


FIG. 4

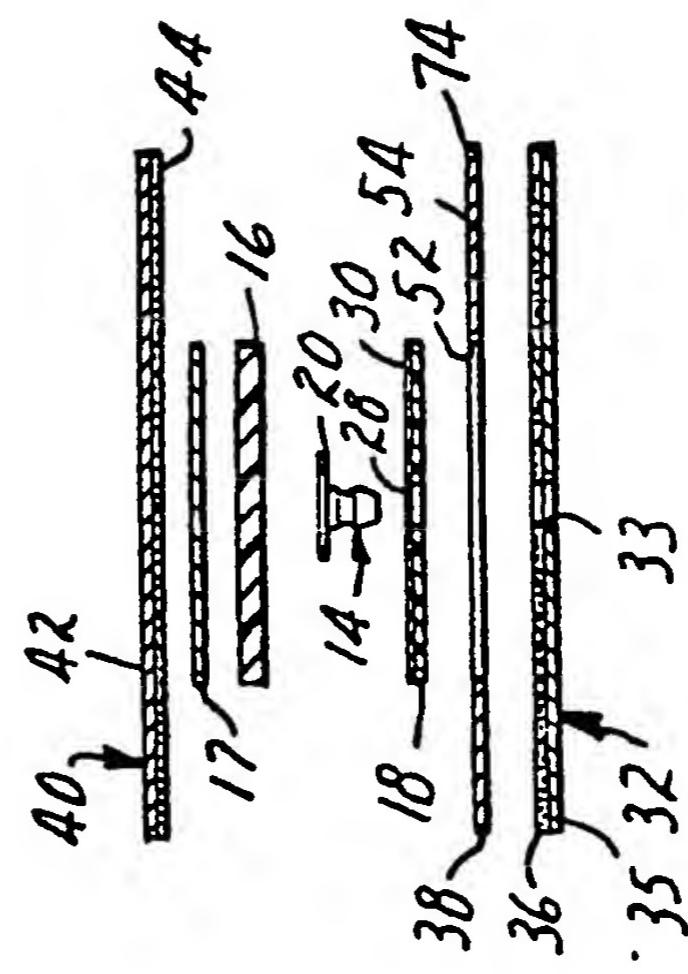


FIG. 5

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